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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/560,494	04/28/2000	Bent Karsten Jakobsen	006090.00022	3480

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EXAMINER
SCHWADRON, RONALD B

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/560,494	JAKOBSEN ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5 and 25-29* is/are pending in the application.

4a) Of the above claim(s) *26,28 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,25,27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/13/06 has been entered.

2. Newly submitted claim 29 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons. The original invention is directed to a method of inhibiting activity of a T lymphocyte using a soluble form of CD8 classified in Class 514, subclass 2, whilst the newly submitted claim is drawn to a method of treating autoimmune disease classified in Class 424, subclass 184.1. The two methods use different ingredients and process steps to achieve different goals. The newly added method encompasses use of nonsoluble CD8 with an exogenous transmembrane domain to treat autoimmune disease mediated by B cells whilst the invention under consideration is limited to a method of inhibiting activity of a T lymphocyte using a specific soluble CD8 molecule wherein the original method also encompasses in vitro use. Therefore the two methods are patentably distinct.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 29 is withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

3. The rejection of claims 1,5,24,25,27 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons elaborated in the previous Office action is withdrawn in view of the amended claims.

4. The rejection of claims 1,5,24,25,27 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons elaborated in the previous Office Action is withdrawn in view of the amended claims.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 1,5,25,27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite in the recitation of "no specific antigen-binding capability other than that of native CD8" because it is unclear what this means or encompasses in the context recited in the claim. The aformentioned phrase is not defined in the specification and has no art recognized meaning. For example, "specific antigen binding capability" can be interpreted as limited to antigen specific binding by variable regions found on B cells or T cells (for example see KPL Technical Notes, page 2, first column wherein specific antigen binding refers to antigen binding mediated by variable regions of antibodies, but does not refer to Fc receptor mediated binding). By this definition, CD8 would not have a "specific antigen binding capability" and therefore it would not be apparent as to what said phrase referred to. In addition, it is unclear as to what "capability" refers to in the context recited in the claim. None of the aformentioned phrases are defined in the specification. Furthermore, even if said term was interpreted as meaning receptor ligand binding (which is not the meaning of the term as per the above KPL Technical Notes reference), the claim discloses in part (vii) that the molecule can have an added peptide or protein for the purpose of purification wherein said molecules function in purification schemes as ligands that are bound by a receptor bound to a solid phase. Therefore it would be unclear as to what said phrase actually encompassed.

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1,5,25,27 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification as originally filed for the recitation of "no specific antigen-binding capability other than that of native CD8" in the context recited in claim 1. Regarding applicants comments, none of the passages of the specification to which applicant refers disclose this limitation. Whilst the limitation under consideration is indefinite for the reasons elaborated above, if "specific antigen binding capability" is interpreted as limited to antigen specific binding by variable regions found on B cells or T cells then the claimed method would exclude conjugates containing variable regions from T or B receptors but permit conjugates using other binding molecules such as Fc. However, there is no such disclosure in the specification as originally filed. The written description provided in the specification is not commensurate in scope with the claimed invention (aka the claimed invention constitutes new matter).

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1,5,25,27 are rejected under 35 U.S.C. 10209 as being anticipated by Tykocinski et al. (5242687) or Tykocinski et al. (5601828) or Tykocinski et al. (5623056) as evidenced by Boursier et al.

Boursier et al. disclose that recombinantly produced soluble CD8alpha forms homodimers upon secretion (see abstract). Therefore, it is an inherent property of said molecule that it forms homodimers when it is recombinantly produced. The Tykocinski

et al. patents have identical disclosures. The instant rejection will refer to the subject matter as per found in 5242687. Tykocinski et al. teach recombinantly produced soluble human CD8 containing amino acids 1-160 of CD8 (see column 5, last paragraph) wherein per as above said molecule will form homodimers. Tykocinski et al. define CD8 as encompassing CD8 alpha (see column 5, second paragraph). Said CD8 is soluble because it contains only the extracellular domain of CD8. Tykocinski et al. teach use of soluble CD8 (see abstract). Tykocinski et al. teach that target cells contacted with CD8 inhibit T cell alloreactivity (see column 15, second paragraph and column 17, first paragraph). Tykocinski teach in vivo administration of said soluble peptides wherein said peptides would inherently block cytotoxicity because the peptides recited in the claim are the same as administered by Tykocinski et al. (see abstract and column 7, paragraph five, and column 14, last paragraph). The sequence recited in the claim represents a portion of the art known CD8 protein. Tykocinski et al. teach CD8alpha soluble multimers (see column 10, penultimate paragraph). Tykocinski et al. teach that the soluble CD8 can used in a liposome wherein the liposome contains a second molecule that is not covalently linked (see column 11, first complete paragraph).

Regarding applicants comments, while the phrase "no specific antigen-binding capability other than that of native CD8" is indefinite for the reasons elaborated above, if the term is interpreted as excluding conjugates containing B or T variable regions then Tykocinski et al. teach the claimed method. Furthermore, Tykocinski et al. teach that the soluble CD8 can used in liposomes wherein the liposome conatins a second molecule that is not covalently linked (see column 11, lines 18-21). The term "soluble CD8" as used in the specification encompasses soluble CD8 bound to liposomes (see specification, page 7, last paragraph, continued on page 8).

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday-Thursday 7:30-6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571 272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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